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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,366	05/16/2001	Richard A. Brauckman	TGXX-1005US	3214

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KNOBLE & YOSHIDA, LLC
Eight Penn Center
Suite 1350
1628 John F. Kennedy Blvd.
Philadelphia, PA 19103

EXAMINER	
RAMANA, ANURADHA	
ART UNIT	**PAPER NUMBER**
3732	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/858,366	BRAUCKMAN ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20-31,33 and 35-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *7-18,20-31,33 and 35-39* is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/9/2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/7/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. (US 5,199,93).

Dake et al. disclose a catheter 10 for endoluminal radiation treatment having an elongated flexible, hollow body 12 with a radioactive means or "source" 14 in radioactive segment 30 of the distal section 20 of the catheter wherein the radioactive means 14 can be any shape and can be placed onto or into body 12 or manufactured into the material of body 12 and provides radiation in an amount from about 10 microcuries to about 100 curies per centimeter length of the radioactive segment 30 (Figures 1 and 9, col. 2, lines 49-54, col. 3, lines 58-68, col. 4, lines 1-8 and lines 34-36, col. 5, lines 19-22 and line 68 and col. 6, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source, as taught by Dake et al., to provide radiation in an amount of 0.5 microcuries to about 300 curies per centimeter length of radioactive segment 30 to treat restenonis since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable Dake et al. in view of Hess (US 5,302,168).

Regarding claim 2, Dake et al. do not disclose a balloon catheter body wherein the radioactive source is bonded to an exterior surface of the catheter body.

Regarding claim 5, Dake et al. do not disclose a retractable sheath.

Hess discloses a device 10 for radiation treatment including a balloon catheter with a balloon or "expandable portion" 36 with radioactive elements or source 38 attached or "bonded" to a balloon 36 wherein when the balloon 36 is expanded in the vicinity of the lesion or treatment site, the radioactive source 38 is forced into contact with the treatment site (col. 3, lines 20-45 and Figures 1, 2 and 4).

Hess also discloses an embodiment of device 10 including a retractable sheath (wire wound for radiation containment or shielding) or shield 24 that can be drawn back when the radiation source 30 in the distal end 18 of device 10 is positioned directly proximate to a treatment site (col. 3, lines 26-40).

Regarding claim 2, it would have been obvious to one of ordinary skill in the art to substitute a balloon catheter as, for example, taught by the Hess reference for the Dake et al. device wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art and the selection of any of these structures would work equally well in the claimed device.

Regarding claim 5, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a retractable sheath around the Dake et al. device, as taught by Hess, for shielding the radiation source.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Carden, Jr. (US 5,405,309).

Dake et al. do not disclose carrier-free palladium 103 as the radiation source.

Carden, Jr. teaches carrier-free palladium 103 (Pd-103) as a safe radiation source for therapeutic purposes (col. 1, lines 40-45, col. 4 and col. 5).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided carrier-free Pd-103 as the radiation source in the device of Dake et al. for enhanced safety.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending application 10/010,250 (US 20020147379) or '379 in view of Dake et al.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 5 of '379 has all the elements of claim 1 except for the claimed radiation amount of 0.5 microcuries to about 300 microcuries per centimeter length of the radioactive portion.

Dake et al. teaches a catheter or tube10 with a radioactive means or "source" 14 in radioactive segment 30 of the distal section 20 of the catheter wherein the radioactive means 14 can be any shape and can be placed onto or into body 12 or manufactured into the material of body 12 and provides radiation in an amount from about 10 microcuries to about 100 curies per centimeter length of the radioactive segment 30 (Figures 1 and 9, col. 2, lines 49-54, col. 3, lines 58-68, col. 4, lines 1-8 and lines 34-36, col. 5, lines 19-22 and line 68 and col. 6, lines 1-5).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source, as taught by Dake

et al., in the '379 device to provide radiation in an amount of 0.5 microcuries to about 300 curies per centimeter length of radioactive segment 30 to treat restenonis since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Claim 5 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 10/010,250 (US 20020147379 or '379) in view of Dake et al. and Hess.

Claim 5 ('379) does not disclose a retractable sheath.

Hess teaches a radiation device 10 having a retractable sheath 24 surrounding a radioactive dose means 30 to provide a measure of shielding for the radioactive dose means wherein sheath 24 can be drawn back when the radiation source 30 in the distal end 18 of device 10 is positioned directly proximate to a treatment site (col. 3, lines 26-40 and col. 4, lines 13-23).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a retractable sheath in the device of the combination of claim 5 ('379) and Dake et al., for radiation shielding as taught by Hess.

Claim 6 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 10/010,250 (US 20020147379 or '379) in view of Dake et al. and Carden, Jr.

Claim 5 ('379) has all the elements of claim 6 except for the claimed radiation amount of 0.5 microcuries to about 300 microcuries per centimeter length of the radioactive portion and carrier-free palladium 103.

Dake et al. and Carden, Jr. supply the missing elements.

Allowable Subject Matter

Claims 7-18, 20-31, 33 and 35-39 are allowed.

Response to Arguments

Applicants' arguments submitted under "REMARKS," in the response filed on September 7, 2004, with respect to the rejections of claims 1-6 under 35 USC 112 paragraphs 1 and 2 and rejections of claims 15-18, 20 and 37 under 35 USC 103(a) are persuasive. Accordingly, the Examiner is withdrawing these rejections.

Applicants' arguments with respect to the rejections of claims 1 and 3-4, 2, 5 and 6 under 35 USC 103(a) are not persuasive for the following reasons.

Dake et al. clearly disclose that the radioactive means can be placed onto or into or manufactured into carrier 12 (col. 5, lines 19-21). Clearly, if the radioactive means is placed onto or into carrier 12 it must be attached or "bonded" or "joined" to carrier 12. Further, this "bonding" must be of sufficient strength otherwise the radioactive means will separate from carrier 12 making it unsuitable for its intended use of preventing restenosis.

It is the Examiner's position that attaching or bonding or joining a radioactive means to a substrate by an adhesive or chemical bonding is very well known in the art. To clarify this position to the Applicants, the Examiner is supplying numerous references with this action (US 6,458,069, US 6,261,320, US 6,042,600, US 5,947,889 and US 5,897,573). Thus, the limitation "bonded to a surface of the distal section of the catheter body with sufficient bond strength," does not patentably distinguish over Dake et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR Anuradha Ramana
December 17, 2004

Cary E. O'Connor
Cary E. O'Connor
Primary Examiner